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January 21, 2020

Dockets Management Staff (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 2061  
Rockville, MD 20852

RE: Modified Risk Tobacco Product Application: Application for Copenhagen Snuff Fine Cut Submitted by Altria Clients Services LLC on behalf of U.S. Smokeless Tobacco Company LLC, Docket No. FDA-2018-N-3261.

The undersigned public health organizations submit these comments on the above-listed tobacco product modified risk application submitted by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Co. LLC (“Altria”) for Copenhagen Snuff Fine Cut, a loose moist snuff tobacco product.<sup>1</sup> The subject applications should be denied for the reasons detailed in these comments.

I. SUMMARY OF REASONS THE COPENHAGEN SNUFF FINE CUT MODIFIED RISK APPLICATION SHOULD BE DENIED

In the subject modified risk application, Altria seeks an order permitting this modified risk claim: “IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer.” The application should be denied for the following reasons:

- **FDA should not grant a modified risk application for a product that does not meet FDA’s own proposed product standard limiting the carcinogen NNN in smokeless tobacco. Instead, that rule should be made final without further delay and smokeless products like Copenhagen Snuff Fine Cut should be taken off the market.**
- **The Applicant introduced insufficient evidence on the impact of the marketing of Copenhagen Snuff Fine Cut with modified risk claims on the increased likelihood of tobacco use initiation by non-users, particularly youth.**
  - Given the history of youth usage of smokeless tobacco and the current crisis of e-cigarette usage, and the statutory requirement for FDA to make

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<sup>1</sup> See 83 Fed. Reg. 47925 (September 21, 2018).

a determination about the impact of a marketing order on youth, it is essential for FDA to require evidence that the marketing of Copenhagen Snuff Fine Cut with the proposed modified risk claim will not increase youth initiation of tobacco products.

- Without justification, the Applicant has failed to present evidence on youth perception of the proposed modified risk claims.
- **The evidence indicates that the marketing of Copenhagen Snuff Fine Cut with the proposed modified risk claims will lead to continued widespread dual use with cigarettes instead of leading substantial numbers of smokers to switch completely to that product.**
  - The experience with smokeless tobacco in the U.S. suggests that Copenhagen Snuff Fine Cut, even with the proposed modified risk claim, will not cause substantial numbers of smokers to quit smoking and switch exclusively to Copenhagen Snuff Fine Cut.
  - The experience with smokeless tobacco in the U.S. suggests that the marketing of Copenhagen Snuff Fine Cut with the proposed modified risk claim will lead to continued widespread dual use with adverse public health consequences, particularly given the history of Copenhagen marketing in the U.S.
  - Research provided by the Applicant shows that the proposed modified risk claim will not lead to changes in behavior among any of the tested tobacco user groups, including smokers or dual users.
- **Altria’s proposed marketing plan does not minimize the risk of exposure of the modified risk claim to youth, nor is it targeted to current adult smokers. It also creates a risk that consumers will be misled into believing that the proposed claim is authorized as to other smokeless products.**

## II. SUMMARY OF STATUTORY MODIFIED RISK STANDARDS

The Copenhagen Snuff Fine Cut application is governed by the standards set out in Section 911 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (Section 911). Section 911 was enacted as a response to the tragic history of false and misleading tobacco industry claims that certain tobacco products were less dangerous than other products that persuaded health-conscious smokers to switch to the “reduced risk” products instead of quitting altogether.

In enacting the Tobacco Control Act, Congress made specific findings about the potential harm to public health from modified risk claims that should guide FDA in its consideration of any modified risk product application. Congress found that “unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health. . . .” Sec. 2(37). Congress also found that “the dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk products are complete, accurate, and relate to the overall disease risk of the product.” Sec. 2(40). Congress determined that it is “essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.” Sec. 2(36).

Under the Tobacco Control Act, a “modified risk tobacco product” is defined as a tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. A product is “sold or distributed” for such a use if, in relevant part,

(1) [its] label, labeling, or advertising, either implicitly or explicitly [represents] that

(i) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(ii) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(iii) the tobacco product or its smoke does not contain or is free of a substance, or

(2) . . . the tobacco product manufacturer has taken any action directed to consumers through the media or otherwise, other than by means of the label, labeling, or advertising. . . . that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or its free of, a substance or substances.

Thus, a modified risk product is defined in terms of the manufacturer’s claims of reduced risk or reduced exposure in marketing the product, as well as its actions that may suggest to consumers that a product reduces risk or exposure to hazardous substances.

Under §911(g)(1), the burden is on the applicant seeking an order allowing the marketing of the product with a modified risk claim to demonstrate that the product “*as it is actually used by consumers* will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.” (emphasis added).

Sec. 911(g)(4) further requires FDA to take into account the following specific empirical factors in determining whether the (g)(1) standard has been met:

- (A) The relative health risks to individuals of the tobacco product that is the subject of the application;
- (B) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
- (C) The increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;
- (D) The risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence.

Thus, FDA must consider not only the effects of the asserted modified risk product on those who use it, but also its population-wide impact on tobacco use initiation, cessation and relapse, including an assessment of the likelihood that smokers would actually switch to the modified risk product. It is not enough for an applicant to show that the product is less hazardous to users than other tobacco products; in order for a modified risk application to be granted, the applicant is required to show that the benefits of risk reduction (considering the likelihood of smokers completely switching to the modified risk product) outweigh the risks of increased initiation or diminished cessation. In short, the statute requires FDA to make scientific judgments not only about the physical effect of the product’s use, but also about the likely responses of potential consumers (both smokers and non-smokers) to the product’s marketing as a modified risk product. It is equally clear that the applicant must show that the use of the modified risk claim will have a *positive* public health benefit to the population as a whole; it is not enough to show the absence of a net detriment to public health.

Finally, the statute makes it clear that the burden falls on the applicant to make the required factual showings; thus, any deficiencies in the evidence presented, or uncertainties about the impact of the proposed modified risk claim on individual tobacco consumers or on the population as a whole, must be resolved against the applicant.

### III. RELEVANT HISTORICAL BASIS FOR SECTION 911

FDA's application of the statutory standards set out in Section 911 must be mindful of the historical context that led Congress to enact those standards, particularly with respect to the current application for Copenhagen Snuff Fine Cut.

The provisions of Section 911 were enacted in response to a massive evidentiary record of fraudulent health and "reduced risk" claims made by tobacco product manufacturers over the course of more than fifty years. Those claims caused millions of Americans to initiate cigarette smoking who otherwise would not have done so and caused millions of American smokers to continue smoking when they otherwise would have quit. In the absence of this massive industry fraud, literally millions of deaths, and untold suffering, would have been avoided.

The voluminous evidence of the industry's use of these false health-related claims was presented to the United States District Court for the District of Columbia in *United States v. Philip Morris, U.S.A., Inc.*<sup>2</sup> and furnished critical support for the court's conclusion that the defendant tobacco companies, including Altria, had engaged in a conspiracy to defraud the American public so massive as to constitute racketeering under federal law. A central component of the fraud was the representation of "light" and "low-tar" cigarettes as safer than other cigarettes, when the companies knew, as actually used by smokers, such cigarettes were no less hazardous. The court found:

Even as they engaged in a campaign to market and promote filtered and low tar cigarettes as less harmful than conventional ones, Defendants either lacked evidence to substantiate their claims or knew them to be false. Indeed, internal industry documents reveal Defendants' awareness by the late 1960s/early 1970s that, because low tar cigarettes do not actually deliver the low levels of tar and nicotine which are advertised, they are unlikely to provide any clear health benefit to human smokers, as opposed to the FTC smoking machine, when compared to regular, full flavor cigarettes.<sup>3</sup>

Thus, Altria and the other industry defendants were found by the court to have violated civil racketeering laws in perpetrating decades-long fraudulent conduct that included the "light" and "low-tar" fraud.

After finding that defendants' fraudulent conduct was likely to continue into the future, the District Court required the defendants, including Altria, to publish corrective statements about the subject matters of the fraud to deter future false and misleading statements. The court ordered Altria and the other defendants to sponsor the corrective statements in newspapers, on

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<sup>2</sup> 449 F. Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).

<sup>3</sup> *Id.* at 430-31.

television, on company websites and on package onserts, including this statement to remedy the “light” and “low-tar” fraud:

A federal court has ordered Altria, R.J. Reynolds Tobacco, Lorillard, and Philip Morris USA to make this statement about low tar and light cigarettes being as harmful as regular cigarettes.

- Many smokers switch to low tar and light cigarettes rather than quitting because they think low tar and light cigarettes are less harmful. They are **not**.
- “Low tar” and “light cigarette smokers inhale essentially the same amount of tar and nicotine as they would from regular cigarettes.
- **All** cigarettes cause cancer, lung disease, heart attacks, and premature death – lights, low tar, ultra lights, and naturals. There is no safe cigarette.

After years of litigation and other delaying tactics by the defendants, including Altria, these corrective statements have now appeared in newspapers and on television, as well as being set forth in onserts on cigarette packs and on the company websites. They serve as reminders of the history of false claims of “reduced risk” products by the tobacco companies, including Altria. In light of that history, particularly the finding by a federal court that Altria and the other RICO defendants are likely to continue their fraudulent conduct, FDA should ensure that the statutory standards, enacted by Congress to prevent a similar public health disaster from ever repeating itself, are rigorously applied to the pending Altria application.

#### IV. THE APPLICATION SHOULD BE DENIED BECAUSE THE LEVEL OF NNN IN COPENHAGEN SNUFF FINE CUT EXCEEDS THE NNN LIMIT TO BE MANDATED BY THE FDA’S PROPOSED RULE ON SMOKELESS TOBACCO

On January 23, 2017, FDA published a proposed rule that would establish a limit of 1.0 microgram per gram of tobacco (on a dry weight basis) of N-nitrosornicotine (NNN), a potent carcinogen, in all finished smokeless tobacco products, which would include Copenhagen Snuff Fine Cut.<sup>4</sup> The pending application makes it clear that, at 3.622 micrograms per gram of tobacco,<sup>5</sup> the level of NNN in Copenhagen Snuff Fine Cut significantly exceeds the maximum level proposed as a product standard by FDA. Thus, in this application, Altria seeks authorization to make a modified risk claim for a product that FDA has proposed to prohibit from the market because such a prohibition would be “appropriate for the protection of the public health.”

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<sup>4</sup> Proposed Rule for Tobacco Product Standard for NNN level in Finished Smokeless Tobacco Products, 82 Fed. Reg. 8004 (January 23, 2017) (Proposed NNN rule).

<sup>5</sup> Altria/U.S. Smokeless Tobacco, 7.1: Product Analysis – HPHC, at 15.

Should the proposed rule become final prior to FDA’s disposition of the pending MRTP application, it would become moot because the product would not conform to the new product standard. Should the proposed rule become final after an MRTP decision, the product would need to be withdrawn. Given the pendency of FDA’s proposal of an NNN product standard for all smokeless tobacco, it makes little sense for the agency to grant the modified risk application for Copenhagen Snuff Fine Cut before it makes a final decision on the proposed product standard.

FDA should issue a final rule establishing the NNN product standard without further delay. The proposed rule is amply supported by scientific evidence establishing that (1) NNN in smokeless tobacco is carcinogenic, (2) reducing the level of NNN in smokeless tobacco products marketed in the United States would substantially reduce the risk of oral cancers for users, and (3) conformance of smokeless tobacco to the proposed product standard is technically feasible, as demonstrated by the presence on the U.S. market of Swedish snus products sold by Swedish Match that already meet the proposed standard.<sup>6</sup> Indeed, FDA estimates that in the 20 years following implementation of the proposed product standard, approximately 12,700 new cases of oral cancer and approximately 2,200 oral cancer deaths would be prevented in the United States. During that 20-year period, approximately 15,200 life years would be gained were the standard to be put into effect.<sup>7</sup>

In light of the substantial benefit to public health FDA anticipates from adoption of its proposed NNN standard, the proposed rule should be made final, and the standard implemented as soon as possible. The proposed rule was issued three years ago and the public comment period has long been closed. There is simply no reason for FDA to further delay making the rule final. Once it does so, the pending MRTP application for Copenhagen Snuff Fine Cut will become moot. It makes little sense for FDA to grant a modified risk application for a product that, according to FDA’s own scientific conclusions, should no longer be permitted on the market.<sup>8</sup>

V. THE APPLICATION SHOULD BE DENIED FOR INSUFFICIENT EVIDENCE ON THE IMPACT OF THE MARKETING OF COPENHAGEN SNUFF FINE CUT WITH MODIFIED RISK CLAIMS ON THE INCREASED LIKELIHOOD OF TOBACCO USE INITIATION BY NON-USERS, PARTICULARLY YOUTH

As noted above, in evaluating the Copenhagen Snuff Fine Cut modified risk application, FDA is required to determine whether granting the application will lead to an “increased or decreased likelihood” that non-users of tobacco products will initiate use of the subject tobacco

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<sup>6</sup> See generally, Proposed NNN Rule, 82 Fed. Reg. at 8010-8026. It should also be noted that the level of NNN in Copenhagen Snuff Fine Cut far exceeds the levels in the Swedish snus products for which FDA has issued modified risk authorization. See Scientific Review of Modified Risk Application (MRTPA) Under Section 911(d) of the FD&C Act – Technical Project Lead, for eight Swedish snus products (Oct. 17, 2019).

<sup>7</sup> Proposed NNN Rule, 82 Fed Reg. at 8026.

<sup>8</sup> Of course, once the proposed NNN rule becomes final and is implemented, Altria will be free to pursue a new MRTP for any of its products that conform to the new NNN standard.

product or some other tobacco product. Because initiation of tobacco products typically occurs when users are young, it is particularly important for FDA to assess the likelihood that the marketing of this product with modified risk claim will lead to initiation by young people. Because Altria’s application offers no evidence of youth perception of the proposed modified risk claims, they should be denied on that ground alone.

- A. Given the history of youth usage of smokeless tobacco and the current crisis of e-cigarette usage, it is particularly important for FDA to require evidence that the marketing of Copenhagen Snuff Fine Cut with modified risk claims will not increase youth initiation of tobacco products.

Tobacco companies have used a variety of strategies to entice youth to use smokeless tobacco: sweet and kid-friendly flavors, sponsorships of events popular with youth, advertisements with youth-oriented messages, and affordable prices.<sup>9</sup> The 2012 Surgeon General’s report, *Preventing Tobacco Use among Youth and Young Adults*, found that the “integration of product design with marketing helped to reverse the mid-twentieth century decline in smokeless tobacco use and spurred a rapid increase in smokeless tobacco use by adolescents and young adult males.”<sup>10</sup>

Given that smokeless tobacco rates among youth have not declined as rapidly as cigarette smoking,<sup>11</sup> and that Copenhagen has been one of the top three most popular snuff brands reported by current smokeless tobacco users aged 12-17 since at least 1999,<sup>12</sup> it is particularly important that Altria be able to demonstrate that marketing Copenhagen Snuff Fine Cut with the proposed modified risk message will not cause youth initiation, including a possible gateway effect to smoking and dual use. There is almost no excuse for not providing data on youth use, interest, and perception of Copenhagen Snuff Fine Cut, given that it has been on the market for decades, as the Applicant has pointed out.

Moreover, nothing in Altria’s marketing plans for this product provide assurance that youth will not be exposed to the modified risk claim, which reinforces why it is important to provide data on the impact of such messaging on youth. As FDA noted in its Briefing Document to TPSAC: “...the applicant’s planned advertising and promotions include non-targeted

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<sup>9</sup> Campaign for Tobacco-Free Kids factsheet, Smokeless Tobacco and Kids, and sources cited therein, <https://www.tobaccofreekids.org/assets/factsheets/0003.pdf>.

<sup>10</sup> U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012, at 539.

<sup>11</sup> U.S. Centers for Disease Control and Prevention (CDC), “Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018,” *Morbidity and Mortality Weekly Report (MMWR)* 68(6):157–164, February 15, 2019, <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6806e1-H.pdf>. CDC, “Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019,” *MMWR* 68(12), December 6, 2019.

<sup>12</sup> Analysis of data from the National Household Survey on Drug Abuse and National Survey on Drug Use and Health, SAMHSA, HHS, Center for Behavioral Health Statistics and Quality.

marketing techniques that may expose youth non-users to advertisements containing modified risk information (e.g., display outside retail outlets, behind the checkout counter).”<sup>13</sup>

The importance of FDA requiring data bearing on the likelihood of increased youth initiation prior to releasing its order on this modified risk application is underscored by the current crisis of e-cigarette usage among young people, which both the Commissioner of the FDA,<sup>14</sup> and the Surgeon General of the United States,<sup>15</sup> declared to have reached “epidemic” proportions. Although there are obvious distinctions between e-cigarettes and smokeless tobacco products, the fact that another kind of highly-addictive “reduced risk” product is proving so appealing to young people, in part because it can be used discreetly, should cause FDA to closely scrutinize the potential impact of modified risk claims for Copenhagen Snuff Fine Cut on youth initiation.

Finally, close post-market surveillance of the impact of modified risk products on youth, although important, is no substitute for rigorous premarket evidence of their likely impact. As we have learned from the meteoric rise of JUUL with teenagers, by the time market surveillance reveals significant uptake of a product by youth, it may be too late to prevent its rapid spread. Not only have e-cigarette prevalence rates skyrocketed, but health professionals are now struggling with treating more and more youth for nicotine addiction, to the point that FDA has conducted two workshops on the issue.<sup>16</sup> Post-market surveillance may be too little, too late. It cannot be considered an adequate substitute for requiring the necessary data as part of the premarket approval process.

B. Without justification, Altria has failed to present evidence on youth perception of the proposed modified risk claims

In its Briefing Document to TPSAC, FDA notes that “[t]he applicant did not submit data or analyses of how its proposed claim may affect youth perceptions of Copenhagen Snuff Fine Cut”<sup>17</sup> as a modified risk product and no “data or analysis of how its proposed claim may affect youth intentions to use Copenhagen Snuff Fine Cut.”<sup>18</sup> No accurate assessment of the impact on the health of the population as a whole can be made without consideration of actual data derived from studies of the perceptions of those under age 18. The total absence of data on youth perception of Copenhagen Snuff Fine Cut, with the proposed modified risk claims, should—standing alone—preclude granting Altria’s application.

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<sup>13</sup> FDA Briefing Document: February 6-7 Meeting of TPSAC on MRTPA MR0000108 from U.S. Smokeless Tobacco Company, at 23 (FDA Briefing Document).

<sup>14</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency’s continued efforts to address growing epidemic of youth e-cigarette use, including potential new therapies to support cessation, November 2, 2018.

<sup>15</sup> Surgeon General’s Advisory on E-Cigarette Use Among Youth, December 18, 2018 (SG Advisory).

<sup>16</sup> 83 Fed Reg. 64752-57. 84 Fed Reg. 12619-21.

<sup>17</sup> FDA Briefing Document, at 29.

<sup>18</sup> *Id.* at 40.

Although Altria did oversample young adults in its consumer perception study, it offers no evidence that young adults are an accurate proxy for youth. FDA noted that it “does not have sufficient information to know whether the claim’s effects among youth would be different than those observed among young adults.”<sup>19</sup> Thus, Altria has provided FDA with no credible evidence on the perception of the product, with its proposed modified risk claim, on youth. Altria offers no justification for this critical gap in its empirical support for the proposed claim.

As FDA’s Draft Guidance for the preparation of Modified Risk Tobacco Product Applications makes clear, FDA requires only that “all study subjects *receiving tobacco products* are current daily tobacco product users at least 21 years of age”<sup>20</sup> (emphasis added). Not only is this limitation not applicable to studies of promotional material such as modified risk claims to determine the effect of such materials on adolescent risk perception or interest in using the product, but the 2012 Draft Guidance makes clear that inclusion of the effect on adolescent perception should be an essential feature of such studies. The Draft Guidance states:

To address the effect of the MRTP on tobacco use initiation, FDA recommends that applicants submit:

- Human studies that evaluate consumer perception of the product, including its labeling, marketing and advertising.

These studies should be designed to provide evidence regarding the likelihood of population benefit or harm from the proposed product, including . . .:

- The likelihood that consumers who have never used tobacco products, *particularly youth and young adults*, will initiate use of the tobacco product;<sup>21</sup> (emphasis added)

Moreover, the Draft Guidance instructs companies to “estimate the attributable risk of all of the various health effects for various types of individuals in the U.S. population, as well as the total number of individuals of each type.” The Draft Guidance goes on to state, “The types of individuals may include, but are not limited to, the following . . . Non-users who initiate tobacco use with the proposed product, *such as youth*, never users, former users” (emphasis added).<sup>22</sup>

Thus, far from prohibiting the testing of such messages on adolescents, the FDA Draft Guidance characterizes such testing as particularly important. In this light, Altria’s failure to provide any evidence of the effect of these messages on adolescent risk perception is an inexplicable omission that ignores FDA’s specific instruction to include that analysis.

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<sup>19</sup> *Id.*

<sup>20</sup> FDA, Draft Guidance, Modified Risk Tobacco Applications, March 2012, at 29 (FDA 2012 Draft Guidance).

<sup>21</sup> *Id.* at 20.

<sup>22</sup> *Id.* at 22.

Moreover, FDA’s Draft Guidance describes how such youth consumer perception research should be done. Recognizing that research among non-smokers, and non-smoking youth in particular, requires care, FDA offered applicants an opportunity to work with the agency to determine the best way to conduct studies involving youth:

When designing consumer perception studies, applicants should take care that the studies themselves do not promote use of the product, particularly among vulnerable populations, such as youth, non-users of tobacco products, and pregnant women. FDA recommends that applicants meet with FDA to discuss research plans before embarking on research with vulnerable populations. Section IX.B of this guidance provides information on requesting a meeting with FDA.<sup>23</sup>

Altria’s failure to assess the impact of the marketing of Copenhagen Snuff Fine Cut as a modified risk product on youth also contravenes recommendations made by the Institute of Medicine’s (IOM) 2012 report, *Scientific Standards for Studies on Modified Risk Tobacco*, which recommended that “FDA should require studies to include populations of special relevance, including (but are not limited to) ... adolescents”<sup>24</sup> and included an assessment of the effects on youth as “an essential element in establishing the public health benefit of an MRTP.”<sup>25</sup> The report included research on adolescents in three of its “Evidence domains relevant to an MRTP application.”<sup>26</sup> The need to consider the effects of promotional statements on youth is vitally important in light of the industry’s documented history of marketing tobacco products in ways that attract adolescents and the role that youth initiation has played—and continues to play—in the recruitment of long-term adult smokers.<sup>27</sup>

According to IOM, perceptions of and intentions to use a given MRTP are also likely to differ by age group. Thus, IOM noted that it is “critical that studies include participants in the following age groups: children ( $\leq 12$  years old), adolescents (13–17 years old), young or emerging adults (18–25 years old), adults ( $\geq 25$  years old).”<sup>28</sup> As noted by IOM, “adolescents’ perceptions of the risks and benefits of cigarette smoking play an important role in adolescents’ decisions to smoke. Given that adolescence is a period of heightened vulnerability for the initiation of tobacco use, it is important to evaluate whether adolescents accurately understand the purported benefits of an MRTP. Of particular importance are adolescents’ perceptions of the risks and benefits of using

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<sup>23</sup> *Id.* at 26.

<sup>24</sup> Institute of Medicine, *Scientific Standards for Studies on Modified Risk Tobacco Products*, December 2011, at 14 (IOM report).

<sup>25</sup> IOM report, at 50.

<sup>26</sup> IOM report, at 7 (Summary).

<sup>27</sup> U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012, at 530-41, 603-27 and sources cited therein (2012 Surgeon General’s Report); *U.S. v. Philip Morris*, 449 F. Supp. 2d, at 561-691.

<sup>28</sup> IOM report, at 174.

the product, and whether they intend to initiate tobacco use with the MRTP rather than a traditional tobacco product because they believe the former is a “safe” alternative.”<sup>29</sup>

Similarly, the IOM report detailed ideas for how research on youth perceptions of risk of MRTPs can be conducted consistent with ethical standards of research.<sup>30</sup> For example, IOM suggests that such research could be appropriately done under the supervision of an independent third party.<sup>31</sup> Such a procedure would make it possible for an applicant to develop evidence regarding the effect of the marketing of a product on this population. IOM noted that, “Survey research or perception/messaging research among non-smokers is acceptable where the non-smokers are not being exposed to the product.”<sup>32</sup> Even in the case of studies that include exposure to a particular tobacco product among non-users (which is not critical in this case), IOM concluded, “Experimental research that exposes non-users to products is ethically problematic; but such research cannot completely be ruled out because it could provide critically valuable information. The ethics, risks, and benefits need to be determined on a case by case basis.”<sup>33</sup>

Despite the express instructions in FDA’s Draft Guidance on the preparation of modified risk applications and the extensive discussion in the IOM report on how research on youth risk perception could appropriately be conducted, Altria has submitted an application that ignores the effects of the proposed modified risk claims on youth. Applications that present no evidence on the effect of modified risk claims on youth initiation or perception of risk cannot possibly meet the public health standard.

Altria’s failure to assess, in any way, the impact of its proposed modified risk message on youth is a particularly significant omission, given data indicating that smokeless tobacco use could be associated with future smoking for youth and young adults. More recently, a study using data from the Population Assessment of Tobacco and Health (PATH) study found that non-smoking youth (12-17 years old) using smokeless tobacco at baseline had higher odds of cigarette smoking initiation and two times the odds of past 30-day cigarette smoking at follow-up a year later compared to non-users.<sup>34</sup> That study reaffirms findings from older studies linking smokeless tobacco use to later cigarette smoking.<sup>35</sup>

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<sup>29</sup> IOM report, at 165.

<sup>30</sup> IOM report, at 10.

<sup>31</sup> IOM report, at 57.

<sup>32</sup> IOM report, at 52.

<sup>33</sup> IOM report, at 52-53.

<sup>34</sup> Watkins, SL, Glantz, SA, Chaffee, BW, “Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015,” *JAMA Pediatrics* 172(2):181-187, 2018.

<sup>35</sup> Tomar, SL, et al., “Is Smokeless Tobacco Use an Appropriate Public Health Strategy for Reducing Societal Harm?,” *International Journal of Environmental Research and Public Health* 6:10-24, 2009, at 16. Severson, H, et al., “Use of smokeless tobacco is a risk factor for cigarette smoking,” *Nicotine and Tobacco Research* 9(12):1331-1337, December 2007. Haddock, CK, et al., “Evidence that smokeless tobacco use is a gateway for smoking initiation in young adult males,” *Preventive Medicine* 32:262-267, 2001. Tomar, S, “Snuff Use and Smoking in U.S. Men: Implications for Harm Reduction,” *American Journal of Preventive Medicine* 23(3):143-149, October 2002.

Moreover, initial smokeless tobacco use is also associated with later multiple tobacco product use. A survey of adolescents and young adults who had ever used tobacco found that those who initiated any tobacco use with smokeless tobacco (or any other non-combustible product) had higher odds of using multiple tobacco products than those who initiated with a combustible product.<sup>36</sup>

Therefore, Altria's failure to develop and submit any data whatsoever on youth perceptions of the proposed modified risk messages is sufficient, by itself, to support denial of the application.

VI. THE APPLICATION SHOULD BE DENIED BECAUSE THE EVIDENCE INDICATES THAT THE MARKETING OF COPENHAGEN SNUFF FINE CUT WITH A MODIFIED RISK CLAIM WILL LEAD TO CONTINUED WIDESPREAD DUAL USE WITH CIGARETTES INSTEAD OF LEADING SUBSTANTIAL NUMBERS OF SMOKERS TO SWITCH COMPLETELY TO COPENHAGEN SNUFF FINE CUT

Data generally do not support the claim that U.S. smokers will use smokeless tobacco products to quit smoking, and that the opposite effect (transitioning from smokeless tobacco to cigarette smoking) is more likely. Even based on its own research, Altria acknowledges the proposed modified risk message will not have a significant impact on intentions to try, use, or switch to Copenhagen Snuff Fine Cut.<sup>37</sup> Instead, the more common trend among U.S. smokers is to become dual users with smokeless tobacco, which does not confer health benefits.

- A. The experience with smokeless tobacco in the U.S. suggests that Copenhagen Snuff Fine Cut, even with modified risk claims, will not cause substantial numbers of smokers to quit smoking and switch exclusively to the product.

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Tomar, S, "Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience," *Nicotine & Tobacco Research* 5(4):561-569, August 2003, <http://www.ncbi.nlm.nih.gov/pubmed/12959794>. See also, Tomar, SL, "Smokeless tobacco use is a significant predictor of smoking when appropriately modeled," *Nicotine & Tobacco Research* 5(4):571-573, August 2003, <http://www.ncbi.nlm.nih.gov/pubmed/12959795>.

<sup>36</sup> Soneji, S, Sargent, J, & Tanski, S, "Multiple tobacco product use among US adolescents and young adults," *Tobacco Control*, 2014, [Epub ahead of print], <http://www.ncbi.nlm.nih.gov/pubmed/25361744>.

<sup>37</sup> "Based on our assessment of the likelihood of use of the candidate product among various subgroups of current tobacco users after viewing the proposed modified risk claim, we demonstrate that:

- there is some increase in likelihood of use of the candidate product, although modest, with greatest use potential among the adult male smoker subgroup;
- there is no statistically significant increase or decrease in trial or switching behaviors;
- there is no statistically significant increase or decrease in the likelihood of candidate product use in conjunction with other products; and
- there is no statistically significant increase or decrease in the likelihood that users who may have otherwise quit using tobacco products will instead use the candidate product."

Altria, Executive Summary, at 35-36.

The data from the U.S. show that smokeless tobacco users are more likely to switch to cigarettes than cigarette smokers are to switch to smokeless tobacco. In its Briefing Document to TPSAC, FDA noted several studies showing that transitioning from exclusive smoking to exclusive smokeless tobacco use is rare, while switching from exclusive smokeless tobacco use to exclusive smoking is more common.<sup>38</sup> One U.S. longitudinal study found that few male smokers stopped smoking and switched to smokeless tobacco (0.3 percent in one year) and few former smokers turned to smokeless tobacco (1.7 percent), concluding that “smokeless tobacco is less useful for quitting smoking among U.S. smokers because in all likelihood they would quit smokeless tobacco before they quit cigarettes.”<sup>39</sup> Another longitudinal study of adolescent and young adult males who were smokers at baseline but did not use smokeless tobacco found that at four-year follow-up, less than one percent (0.8 percent) switched to smokeless tobacco and 3.6 percent continued to smoke and became smokeless tobacco users as well.<sup>40</sup>

Even exposing smokers to the proposed modified risk messaging did not change their behavior. Altria’s research “found no evidence that the proposed claim would promote switching. Findings from the study show that the modified risk claim did not significantly increase intentions to try, use, switch to, or dual use Copenhagen Snuff among smokers planning to quit...”<sup>41</sup> FDA also stated, “In addition, there was no evidence that the modified risk claim would affect smokers’ intentions to quit smoking cigarettes or tobacco users’ intentions to quit all tobacco.”<sup>42</sup> FDA reinforced the findings of Altria’s study, noting “The null results appear credible, as the study used acceptable measures of behavioral intentions and appeared to have adequate statistical power to detect small effect sizes. While self-reported behavioral intentions are an imperfect predictor of actual future behavior, the Applicant’s research provides little evidence that the proposed claim would increase use of the product among adult consumers.”<sup>43</sup>

These findings are not surprising, given the conclusion from the 2008 Update of the U.S. Public Health Service Clinical Practice Guidelines regarding tobacco cessation: “the use of smokeless tobacco products is not a safe alternative to smoking, nor is there evidence to suggest that it is effective in helping smokers quit.”<sup>44</sup>

As noted in Section II, *supra*, the absence of harm from a proposed modified risk claim is insufficient to support a modified risk order; rather, the applicant has the burden of demonstrating a positive public health benefit from marketing the product with the proposed

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<sup>38</sup> FDA Briefing Document, at 32.

<sup>39</sup> Zhu, S-H, et al., “Quitting Cigarettes Completely or Switching to Smokeless: Do U.S. Data Replicate the Swedish Results?,” *Tobacco Control* 18:82-87, 2009, at 86.

<sup>40</sup> Tomar, S, “Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience,” *Nicotine & Tobacco Research* 5(4):561-569, August 2003, <http://www.ncbi.nlm.nih.gov/pubmed/12959794>.

<sup>41</sup> FDA Briefing Document, at 35.

<sup>42</sup> FDA Briefing Document, at 35.

<sup>43</sup> FDA Briefing Document, at 40.

<sup>44</sup> Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update*, U.S. Public Health Service Clinical Practice Guideline, May 2008, [http://www.surgeongeneral.gov/tobacco/treating\\_tobacco\\_use08.pdf](http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf).

claim. Data submitted by Altria does not demonstrate that benefit, but instead merely show no change in behavior from exposure to the modified risk claim. Thus, there is no reason to believe that marketing the product with the proposed claim will lead smokers to switch completely to Copenhagen Snuff Fine Cut so as to yield a public health benefit.

- B. The experience with smokeless tobacco use in the U.S. suggests that the marketing of Copenhagen Snuff Fine Cut with a modified claim will lead to continued widespread dual use, with adverse effects on public health, rather than switching to exclusive smokeless use.

An alternative to switching completely is using both products concurrently (dual use). Dual use has extremely important health consequences. Dual use may prolong duration of smoking, which plays a major role in increasing risks of developing smoking-related diseases.<sup>45</sup> In its application, Altria recognized that more than one-third of adult smokeless tobacco users in the U.S. is a dual user with cigarettes.<sup>46</sup>

This question of individual risks from dual use also has population-level implications. Dual or multiple product use is not a trivial concern in the U.S. A substantial body of evidence supports the proposition that health benefits to an individual from quitting smoking occur only if the individual completely quits smoking. Merely reducing the number of cigarettes smoked or engaging in dual use of cigarettes and other tobacco products does not substantially reduce the health risk, as several U.S. Surgeon General's Reports and other studies have indicated that the risk of cardiovascular disease and other smoking-related diseases depends largely on the length of time a person smokes, not the number of cigarettes smoked.<sup>47</sup> According to the CDC, "If you only cut down the number of cigarettes you smoke by adding another tobacco product...you still

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<sup>45</sup> U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*, U.S. Centers for Disease Control and Prevention (CDC), Office of Smoking and Health (OSH), 2010, at 9. HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, OSH, 2012, at 22, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>. Schane, RE, Ling, PM, & Glantz, SA, "Health Effects of Light and Intermittent Smoking: A Review," *Circulation* 121(3):1518-1522, 2010. Tverdal, A & Bjartveit, K, "Health Consequences of Smoking 1-4 Cigarettes per Day," *Tobacco Control* 14(5), 2005. Hackshaw, A, et al., "Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports," *BMJ* 360:j5855, <http://doi.org/10.1136/bmj.j5855>, 2018.

<sup>46</sup> Altria, Executive Summary, at 7.

<sup>47</sup> U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease*, U.S. Centers for Disease Control and Prevention (CDC), Office of Smoking and Health (OSH), 2010, at 9. HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, CDC, OSH, 2012, at 22, <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html>. Schane, RE, Ling, PM, & Glantz, SA, "Health Effects of Light and Intermittent Smoking: A Review," *Circulation* 121(3):1518-1522, 2010. Tverdal, A & Bjartveit, K, "Health Consequences of Smoking 1-4 Cigarettes per Day," *Tobacco Control* 14(5), 2005. Hackshaw, A, et al., "Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports," *BMJ* 360:j5855, <http://doi.org/10.1136/bmj.j5855>, 2018.

face serious health risks. Smokers must quit smoking completely to fully protect their health – even a few cigarettes a day are dangerous.”<sup>48</sup>

While *complete switching* to Copenhagen Snuff Fine Cut might “significantly” reduce smokers’ risk of certain smoking-related diseases, as Altria asserts in its application,<sup>49</sup> incomplete switching (dual use or merely cutting down smoking) keeps smokers’ risks of disease elevated. One study concluded, “Because the health risks associated with cigarettes and ST [smokeless tobacco] are different in some respects, and because their effects may be additive if not synergistic, the concomitant use of cigarettes and ST may increase the risk of tobacco-attributable death and disease relative to use of either product alone.”<sup>50</sup> Another, more recent study determined that health issues are more likely among people who used both smokeless tobacco and cigarettes compared to those who used only one product.<sup>51</sup>

In addition to the potential additive health risks, dual use may keep smokers smoking longer, which also continues to elevate their health risks. Several studies have found that dual users have similar or lower likelihood of quitting or attempting to quit smoking compared to exclusive cigarette smokers.<sup>52</sup> One study has found that, while dual users were more likely to make a quit attempt compared to exclusive smokers, they tended to relapse more quickly compared to exclusive smokers, and had comparable 30-day abstinence levels to exclusive smokers.<sup>53</sup> Dual users of smokeless tobacco and cigarettes use smokeless tobacco to maintain their cigarette addiction, not to quit smoking,<sup>54</sup> and do not believe that smokeless products can help them quit smoking.<sup>55</sup> One study found that smokeless users who used these products to cut down on smoking were no more likely to stop using cigarettes compared to those smokers who

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<sup>48</sup> CDC, “Powerful new Tips from Former Smokers” ads focus on living with vision loss and colorectal cancer,” CDC Press Release, March 26, 2015, <http://www.cdc.gov/media/releases/2015/p0326-tips.html>. See also: CDC, “Dual Use of Tobacco Products.” <http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html#ten>.

<sup>49</sup> Altria, Executive Summary, at 29. Altria Briefing Document, at 27.

<sup>50</sup> Wetter, D, et al., “Concomitant Use of Cigarettes and Smokeless Tobacco: Prevalence, Correlates, and Predictors of Tobacco Cessation,” *Preventive Medicine* 34:638-648, 2002.

<sup>51</sup> Hernandez, SL, et al., “Relationships Among Chewing Tobacco, Cigarette Smoking, and Chronic Health Conditions in Males 18–44 Years of Age,” *Journal of Primary Prevention* 38(5):505-514, 2017.

<sup>52</sup> Schauer, GL, Pederson, LL, & Malarcher, AM, “Past Year Quit Attempts and Use of Cessation Resources Among Cigarette-Only Smokers and Cigarette Smokers Who Use Other Tobacco Products,” *Nicotine & Tobacco Research* 18(10):41-47, 2016. Klesges, RC, et al., “Tobacco Use Harm Reduction, Elimination, and Escalation in a Large Military Cohort,” *American Journal of Public Health* 100(12):2487-2492, December 2010, at 2490 (“Importantly, dual users were less likely to become tobacco abstinent than were smokers or smokeless tobacco users . . .”); Wetter, D, et al., “Concomitant Use of Cigarettes and Smokeless Tobacco: Prevalence, Correlates, and Predictors of Tobacco Cessation,” *Preventive Medicine* 34:638-648, 2002, (“Concomitant users were significantly less likely to quit using tobacco over the course of 4 years than were users of cigarettes or ST.”).

<sup>53</sup> Messer, K, et al., “Cigarette smoking cessation attempts among current US smokers who also use smokeless tobacco,” *Addictive Behaviors* 51:113-119, 2015.

<sup>54</sup> McClave-Regan, AK & Berkowitz, J, “Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of ‘dual users’,” *Tobacco Control* 20:239-242, 2011, <http://www.ncbi.nlm.nih.gov/pubmed/21172853>.

<sup>55</sup> McClave-Regan, AK & Berkowitz, J, “Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of ‘dual users’,” *Tobacco Control* 20:239-242, 2011.

did not use smokeless tobacco,<sup>56</sup> and another study found that smokers saw these products as temporary, rather than complete substitutes.<sup>57</sup>

At the February 2019 TPSAC meeting, Altria singled out dual users as “a logical harm reduction opportunity,” while ignoring the research that most dual users do not transition to exclusive smokeless tobacco use.<sup>58</sup> In its Briefing Document to TPSAC, FDA noted that, while Altria cited studies showing higher rates of switching to exclusive smokeless use among dual users compared to exclusive smokers, the company omitted findings from one of the cited studies that found higher rates of dual users switching to exclusive smoking or continuing to dual use for an additional four years.<sup>59</sup> FDA also referenced additional studies showing similar patterns of more dual users switching to cigarettes than exclusive smokeless use, and sustained dual use at follow-up.<sup>60</sup>

Altria’s own research found that the addition of modified risk messages will not impact the behavior of dual users. FDA’s Briefing Document noted, “Of particular interest is the claim’s null effect on intentions to switch to Copenhagen Snuff among current dual users of moist snuff and cigarettes.”<sup>61</sup> In other words, even if dual users were primed to switch to exclusive smokeless tobacco use because they were already using smokeless tobacco, Altria’s data show that the proposed modified risk messaging had no effect on encouraging them to do so. Despite Altria’s purported “opportunity” with dual users, nothing in the application indicates that exposure to the proposed claim will make any impact on this population. Again, because a decision by FDA to authorize a modified risk product cannot be based merely on an absence of harm, but rather requires evidence of a positive benefit for public health, FDA should not grant the modified risk order based on the available evidence.

- C. Given the existing patterns of dual use in the U.S., it is significant that Altria failed to submit information about the perception of health impacts from incomplete switching.

Just as Altria argues that consumers should understand the relative risks of smokeless tobacco use compared to cigarette smoking,<sup>62</sup> because dual use of cigarettes and smokeless tobacco is common in the U.S., it is just as important for consumers to understand the health risks of dual use. However, studies conducted by Altria found that the proposed message had

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<sup>56</sup> Kasza, KA, et al., “Cigarette Smokers’ Use of Unconventional Tobacco Products and Associations With Quitting Activity: Findings From the ITC-4 U.S. Cohort,” *Nicotine & Tobacco Research* 16(6):672-681, June 2014, <http://www.ncbi.nlm.nih.gov/pubmed/24376276>.

<sup>57</sup> O’Connor, RJ, et al., “US smokers’ reactions to a brief trial of oral nicotine products,” *Harm Reduction Journal* 8:1-10, 2011, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3032705/pdf/1477-7517-8-1.pdf>.

<sup>58</sup> Altria presentation to TPSAC, February 6, 2019, Transcript, <https://www.fda.gov/media/122002/download>, at 153-154.

<sup>59</sup> FDA Briefing Document, at 32.

<sup>60</sup> FDA Briefing Document, at 32.

<sup>61</sup> FDA Briefing Document, at 35.

<sup>62</sup> Altria Briefing Document, at 14.

virtually no impact on behavior among any of the tobacco use groups.<sup>63</sup> That would mean that the dual users exposed to the proposed message still were not motivated to drop cigarettes altogether, despite the specific instruction to do so.

In interviews, Altria found that using the terms “switching completely” and “exclusive use” in the proposed modified risk claim were understood by interviewees to mean complete substitution.<sup>64</sup> Altria seems to have made the assumption that, because it used the terms “switching completely” and “exclusive use” in the proposed modified risk claim, cigarette smokers and dual users will act on that suggestion because of the prospect of better health. However, FDA noted that Altria “did not assess how consumers perceive the health risks associated with partially switching from combusted cigarettes to Copenhagen Snuff Fine Cut. ...[N]either the claim nor the LLA materials describe the health effects of partial switching. This is important, as partial switching and long-term dual use are common use patterns....”<sup>65</sup> Informing smokers that complete switching to Copenhagen Snuff Fine Cut will reduce the risk of lung cancer, without also informing them of the health effects of incomplete switching (dual use), is likely to perpetuate dual use, not discourage it, as reflected in Altria’s own data.

## VII. THE APPLICATION SHOULD BE DENIED BECAUSE THE PROPOSED MARKETING PLAN DOES NOT LIMIT THE EXPOSURE OF THE MODIFIED RISK CLAIM TO ADULT SMOKERS

Altria asserts that its proposed marketing plan using the proposed modified risk message can “increase ... the adoption of the candidate product by smokers over time” and “encourage cigarette smokers to switch to the less harmful candidate product, especially among those already receptive to non-combustible products like MST.”<sup>66</sup> The company also intends to “limit our reach to unintended audiences” in its marketing plan.<sup>67</sup> Without exception, though, each medium of Altria’s proposed marketing plan is inconsistent with its purported goals and seems merely to promote Copenhagen Snuff Fine Cut among existing Copenhagen users. It is clear that Altria is not prepared to take all the necessary steps to both limit the exposure of the proposed modified risk message to youth and target the messaging to adult smokers.

Altria’s marketing plan includes print advertisements in magazines, direct mail to “adult tobacco consumers,” emails to adult tobacco consumers, a pop-up on the Copenhagen website, a promotional card to be distributed at “USSTC’s Copenhagen® qualified adult-only facilities or during Copenhagen® brand promotions at adult-only facilities” or at retail stores, labels on the

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<sup>63</sup> FDA Briefing Document, at 40.

<sup>64</sup> Altria Briefing Document, at 28-29.

<sup>65</sup> FDA Briefing Document, at 28.

<sup>66</sup> Altria MRTP application, 4.1: Labels, Labeling, and Advertising, at 3.

<sup>67</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 3.

bottom of Copenhagen Snuff Fine Cut cans, and at the point-of-sale.<sup>68</sup> None of these media focus solely on recruiting adult smokers, and in fact can expose youth to such marketing.

A. The proposed marketing plan is not targeted to adult smokers.

Altria is the parent company of a cigarette subsidiary, smokeless tobacco subsidiary, cigar subsidiary, and has a large share in the e-cigarette company, Juul Labs.<sup>69</sup> If the company is serious about having adult smokers switch completely, then its marketing should focus primarily on those individuals, and it should be in the best position than any other tobacco company to do so. However, the application does not include any marketing activity solely targeted at adult smokers, but instead employs methods to reassure current smokeless tobacco users about the smokeless tobacco products they are already using and thus promote their continued use.

Placing a label with the proposed modified risk claim on the bottom cans of Copenhagen Snuff Fine Cut, as proposed by the Applicant,<sup>70</sup> exposes primarily current users of Copenhagen Snuff Fine Cut to the message. Those users would not need the modified risk claim to be persuaded to purchase the product because they are already doing so, and indeed, they may not be smokers at all. Instead, to reach primarily adult smokers, onserts or inserts could be attached to cigarette packs – especially since Altria manufactures the dominant brand of cigarettes, Marlboro – to which it can attach them. This is not a novel idea. In announcing its purchase of 35 percent stake in Juul Labs, Inc., Altria’s press statement included, “Altria will enable JUUL to reach adult smokers with direct communications through cigarette pack inserts.”<sup>71</sup> Yet its modified risk application for Copenhagen Snuff Fine Cut proposes no such marketing effort directed at smokers.

Similarly, Altria proposes placing a pop-up window “on FreshCope.com, the branded website for Copenhagen@.”<sup>72</sup> Only people who have taken the time to register and get age-verified<sup>73</sup> to enter the Copenhagen website can access it; presumably those individuals already use Copenhagen products, or have enough interest in the brand to go through that effort. There is no indication that those registered on the Copenhagen website are largely smokers, which Altria claims it wants to help stop smoking. Most likely, then, the only consumers who will see the proposed pop-up screen are already Copenhagen smokeless tobacco users.

Altria also does not specify that the proposed modified risk claim will be sent to adult smokers on its mailing or email lists, but only vaguely refers to “adult tobacco consumers.” As

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<sup>68</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 4-6.

<sup>69</sup> Altria website, “Our Companies; At-A-Glance,” <https://www.altria.com/About-altria/our-companies/at-a-glance/Pages/default.aspx>, accessed January 10, 2020.

<sup>70</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 6.

<sup>71</sup> Altria, “Altria Makes \$12.8 Billion Minority Investment in JUUL to Accelerate Harm Reduction and Drive Growth,” Press Statement, December 20, 2018, <http://investor.altria.com/file/Index?KeyFile=396169695>.

<sup>72</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 5.

<sup>73</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 3.

presented in the direct marketing examples,<sup>74</sup> those consumers could very well be those on Copenhagen’s mailing list for smokeless tobacco products. Again, that would largely expose existing smokeless tobacco users to the messaging, and not adult cigarette smokers. It is entirely feasible for Altria to send the messages to adult smokers on its cigarette brand mailing lists, since this is something else that Altria announced that it would do for Juul Labs.<sup>75</sup>

As one final example, Altria’s proposed distribution of promotional cards at “Copenhagen® qualified adult-only facilities” and during Copenhagen promotions likely will reach primarily current smokeless tobacco users, not adult smokers.

B. The proposed marketing plan would still expose millions of youth to the modified risk claim.

Far from narrowing the audience of its proposed modified risk claims, Altria’s proposed plans to place advertising with the proposed modified risk claim in magazines and at the point of sale still mean that millions of youth will be exposed to them. It is clear that Altria’s marketing plan is incompatible with its intentions to “limit our reach to unintended audiences.”<sup>76</sup>

The large majority of tobacco company marketing spending is at the retail level. In 2018 (the most recent available), the top five smokeless tobacco companies – of which Altria is the largest – spent \$25.3 million on point-of-sale marketing, such as materials displayed or distributed at the point of sale.<sup>77</sup> Point-of-sale advertising and promotions are effective because they target and attract shoppers at the exact place and time when they can buy a specific product. When it comes to youth, the tobacco industry’s marketing has been found to impact not only what products and brands youth use, but also the chances that youth will start using tobacco products.<sup>78</sup>

As a result of this spending, tobacco company marketing at the point of sale is pervasive. A national study of point-of-sale marketing published in 2014 found that almost all tobacco retailers (96 percent) had at least one tobacco marketing material, with an average of nearly 30 marketing materials per store. About one in ten tobacco retail stores displayed tobacco products at heights of less than three feet, and 10 percent of stores displayed them within 12 inches of

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<sup>74</sup> Altria, 4.1: Labels, Labeling, and Advertising, at Appendices 4.1-2, 4.1-3, 4.1-4.

<sup>75</sup> “Altria will enable JUUL to reach adult smokers with direct communications through ... mailings to adult smokers via Altria companies’ databases.” Altria, “Altria Makes \$12.8 Billion Minority Investment in JUUL to Accelerate Harm Reduction and Drive Growth,” Press Statement, December 20, 2018, <http://investor.altria.com/file/Index?KeyFile=396169695>.

<sup>76</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 3.

<sup>77</sup> U.S. Federal Trade Commission (FTC), *Smokeless Tobacco Report for 2018*, 2019, <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2018-smokeless-tobacco-report-2018/p114508smokelesstobaccoreport2018.pdf>. [Data for top 5 manufacturers only].

<sup>78</sup> U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.

candy.<sup>79</sup> State and city-specific studies have also documented the ubiquity of tobacco company marketing in their communities.<sup>80 81 82 83</sup>

In its application for Copenhagen Snuff Fine Cut, Altria has proposed to place its proposed point-of-sale marketing signs “behind the checkout counter and within 48” of where ST products are sold,”<sup>84</sup> in a display area often called a “powerwall.” These “powerwalls” of branded imagery that makes tobacco products more visible, more attractive and more enticing.<sup>85</sup> Tobacco companies know that that “eye level is buy level,”<sup>86</sup> so they pay retailers large sums of money to put their tobacco products on ‘good’ shelving space (slotting allowances). In addition, tobacco companies often have signs advertising their tobacco products on doors of retail stores and in retail store parking lots that are directly at kids’ eye level. Altria also proposes posting signs in those areas,<sup>87</sup> which again, exposes kids to the modified risk message. FDA recognized this discrepancy in its presentation to TPSAC, with CTP’s Dr. Benjamin Apelberg stating, “Although the Applicant stated in its application that its marketing and advertising plans have features that will reduce the risk of youth uptake, FDA does note that the Applicant’s plan to display advertisements outside retail outlets and at the checkout counter may expose youth nonusers to advertisements containing modified risk information.”<sup>88</sup>

The pervasiveness of tobacco company marketing at the point of sale becomes even more significant when one considers the high number of tobacco retailers. There are an estimated 375,000 tobacco retailers in the U.S. (more than the number of Starbucks or McDonald’s), and

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<sup>79</sup> Center for Public Health Systems Science. *Point-of-Sale Report to the Nation: The Tobacco Retail and Policy Landscape*, St. Louis, MO: Center for Public Health Systems Science at the Brown School of Social Work at Washington University in St. Louis and the National Cancer Institute, State and Community Tobacco Control Research, 2014.

<sup>80</sup> Schleicher, N, et al., “Tobacco Marketing in California’s Retail Environment (2008-2011), Final report for the California Tobacco Advertising Survey,” Stanford, CA: Stanford Prevention Center; July 2013.

<sup>81</sup> Philadelphia Department of Public Health, “Retail Advertising for Tobacco Products and Sugary Beverages in Philadelphia,” 2013,

[http://www.phila.gov/health/pdfs/Tobacco%20and%20sugary%20drinks%20ad%20report\\_82013\\_final.pdf](http://www.phila.gov/health/pdfs/Tobacco%20and%20sugary%20drinks%20ad%20report_82013_final.pdf).

<sup>82</sup> New York Public Interest Research Group, “Overexposed: Big Tobacco’s Advertising Saturation Around New York City Schools,” 2013, <http://www.nypirg.org/health/overexposed/overexposed.pdf>.

<sup>83</sup> Glanz, K, Sutton, NM, & Jacob Arriola, KR, “Operation storefront Hawaii: Tobacco advertising and promotion in Hawaii stores,” *Journal of Health Communication* 11(7):699-707, 2006.

<sup>84</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 6.

<sup>85</sup> Feighery, EC, et al., “Retailer participation in cigarette company incentive programs is related to increased levels of cigarette advertising and cheaper cigarette prices in stores,” *Preventive Medicine* 38(6):876-84, 2004; Feighery, E, et al., “Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California,” *Tobacco Control* 10:184-188, 2001; Feighery, EC, et al., “How the tobacco companies ensure prime placement of their advertising and products in stores: Interviews with retailers about tobacco company incentive programs,” *Tobacco Control* 12:184-188, 2003; Rogers, T & Feighery, E, “Community Mobilization to Reduce Point Of Purchase Advertising of Tobacco Products,” *Health Education Quarterly* 22(4):427-43, November 1995.

<sup>86</sup> Pollay, RW, “More than meets the eye: on the importance of retail merchandising,” *Tobacco Control*, 16(4), February 2007.

<sup>87</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 6.

<sup>88</sup> FDA Presentation to TPSAC, February 6, 2019, Transcript, <https://www.fda.gov/media/122002/download>, at 230.

the majority of them are convenience stores.<sup>89</sup> This adds up to a massive amount of tobacco advertising and marketing at the point of sale. With nearly half of adolescents visiting a convenience store at least once a week,<sup>90</sup> the chance of a teenager being repeatedly and regularly exposed to tobacco company marketing is high.

Data from the National Youth Tobacco Survey (NYTS) show that 77.3 percent of middle school students and 81.2 percent of high school students were exposed to tobacco advertisements in stores in 2019.<sup>91</sup> According to data from the 2011 NYTS, middle school students who reported seeing tobacco advertising in stores were more likely to be susceptible to trying cigarettes than their peers who did not see such advertising.<sup>92</sup>

The majority of research on point-of-sale tobacco product advertising focuses on cigarettes, but the overall impact from smokeless tobacco marketing at the point of sale is likely similar. Tobacco company advertising at the point of sale encourages youth initiation and discourages cessation.<sup>93</sup> In fact, the U.S. Surgeon General concluded in 2012 that the advertising and promotional efforts of the tobacco companies—including price-reducing promotions—cause the initiation and progression of tobacco use among youth.<sup>94</sup>

Altria has proposed attaching coupons to some of its promotional materials with the modified risk claim for Copenhagen Snuff Fine Cut. Experience with cigarette coupons suggests this is likely to have the primary effect of encouraging initiation and continued use of the Copenhagen product. A 2015 study, using data from the 2012 NYTS, concluded that exposure to tobacco coupons may encourage youth smoking and hinder cessation. Receipt of tobacco coupons was associated with a higher likelihood of being susceptible to cigarette smoking among non-smoking youth, a lower likelihood of feeling confident about quitting among youth smokers, and a higher likelihood of intention to purchase cigarettes among youth smokers and

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<sup>89</sup> Center for Public Health Systems Science. *Point-of-Sale Report to the Nation: The Tobacco Retail and Policy Landscape*, 2014.

<sup>90</sup> Sanders-Jackson, A, et al., “Convenience store visits by US adolescents: Rationale for healthier retail environments,” *Health & Place* 34:63-66, 2015.

<sup>91</sup> CDC, “Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019,” *MMWR*, 68, December 6, 2019, <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

<sup>92</sup> Dube, S, et al. “Pro-Tobacco Influences and Susceptibility to Smoking Cigarettes Among Middle and High School Students—United States, 2011,” *Journal of Adolescent Health*, 52:S45-S51, 2013.

<sup>93</sup> Paynter, J & Edwards, R, “The impact of tobacco promotion at the point of sale: A systematic review,” *Nicotine and Tobacco Research* 11(1):25-35, January 2009; Slater, SJ, et al., “The impact of retail cigarette marketing practices on youth smoking uptake,” *Arch Pediatr Adolesc Med* 161(5):440-445, May 2007; Wakefield, M, Germain, D, & Henriksen, L, “The effect of retail cigarette pack displays on impulse purchase,” *Addiction* 103(2):322-328, Feb 2008. Center for Public Health Systems Science, *Point-of-Sale Report to the Nation: The Tobacco Retail and Policy Landscape*, 2014.

<sup>94</sup> HHS, *Prevention Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012, [http://www.cdc.gov/tobacco/data\\_statistics/sgr/2012/index.htm](http://www.cdc.gov/tobacco/data_statistics/sgr/2012/index.htm).

experimenters.<sup>95</sup> In 2018, the top five smokeless tobacco companies, including Altria, spent \$57.1 million on printing, promoting, and redeeming coupons for smokeless tobacco products.<sup>96</sup>

All of the marketing at the point of sale leads to one thing – youth access. Data from the 2018 NYTS show that, among middle and high school students who reported buying tobacco products themselves, more than half (57.7 percent) said that they bought it in a gas station/convenience store. With other types of retailers added in, eight in ten middle and high schoolers said that they bought their tobacco products from a gas station/convenience store, grocery store, or drug store.<sup>97</sup>

Furthermore, as noted previously, national data show that Copenhagen has been one of the top three most popular snuff brands reported by current smokeless tobacco users aged 12-17 since at least 1999.<sup>98</sup> This fact makes it even more important that the proposed modified risk marketing for Copenhagen Snuff Fine Cut be limited to adult smokers.

C. The potential impact of proposed marketing plan is not tailored to Copenhagen Snuff Fine Cut.

Though Altria’s proposed modified risk message refers to “this product,” none of the proposed marketing pieces identify the specific product to which the message applies. Unlike images of other Copenhagen products advertised in Altria’s other marketing materials, which show cans that indicate the specific variety of Copenhagen (i.e., “long cut” or “pouches”),<sup>99</sup> the image of the Copenhagen snuff can used in all of the proposed advertisements looks generic, and the advertising pieces do not mention “fine cut” at all.<sup>100</sup>

This is troubling because viewers may misinterpret the modified risk message to apply to any and all Copenhagen snuff products, not just the Fine Cut product for which Altria has submitted this application. Data on the differences in health outcomes from using Fine Cut vs. Long Cut (or any other variety of moist snuff) are not provided in the application, and FDA stated, “Such studies did not directly test the potential of Copenhagen Snuff Fine Cut to induce toxicities that may then be compared to never use, other smokeless tobacco products, or cigarettes.”<sup>101</sup> Because Altria has submitted this application specifically for the Fine Cut variety

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<sup>95</sup> Choi, K, “The associations between exposure to tobacco coupons and predictors of smoking behaviours among U.S. youth,” *Tobacco Control*, published online first, April 16, 2015.

<sup>96</sup> FTC, *Smokeless Tobacco Report for 2018*, 2019, <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2018-smokeless-tobacco-report-2018/p114508smokelesstobaccoreport2018.pdf>. [Data for top 5 manufacturers only].

<sup>97</sup> Liu, ST, “Youth Access to Tobacco Products in the United States, 2016-2018,” *Tobacco Regulatory Science* 5(6):491-501, 2019.

<sup>98</sup> Analysis of data from the National Household Survey on Drug Abuse and National Survey on Drug Use and Health, SAMHSA, HHS, Center for Behavioral Health Statistics and Quality.

<sup>99</sup> See, for instance, Copenhagen email from October 3, 2019, advertising “new” Smooth Wintergreen Copenhagen Long Cut, courtesy of Trinkets and Trash at <http://www.trinketsandtrash.org/detail.php?artifactid=14934>.

<sup>100</sup> Altria, 4.1: Labels, Labeling, and Advertising, at Appendices 4.1-1, 4.1-2, 4.1-4, 4.1-5, 4.1-7, 4.1-9.

<sup>101</sup> FDA Briefing Document, at 10.

and not for all of its Copenhagen products, the company should be required to show that its proposed modified risk message will be applied, and understood to apply, only to this specific product, and not other Copenhagen versions.

Altria has submitted limited data on the relative risk of developing lung cancer from switching from cigarette smoking to the specific Copenhagen Snuff Fine Cut product that is the subject of this application. Instead, it has asked FDA to assume that, since most of the published epidemiological studies on long-term health risk have been conducted on older moist snuff products, and Copenhagen as a brand has had a large share of that moist snuff market, then the health risks attributable to the moist snuff category must largely be based on the impact of Copenhagen moist snuff use.<sup>102</sup> FDA noted in its Briefing Document to TPSAC, “The peer-reviewed and published studies presented in the application on the health risks of U.S. smokeless tobacco products reflect the products that were on the market and being used by study participants at the time the studies were conducted, and are not necessarily the same product that is the subject of this application.”<sup>103</sup>

If Altria is arguing that the findings from general health risk studies are relevant to this Copenhagen product because Copenhagen brand products have had a large part of the moist snuff market share overall, then Altria should have submitted applications for each of its Copenhagen moist snuff styles, not just the Fine Cut version, just as Swedish Match had submitted multiple modified risk tobacco product applications for eight General snus products. Instead, by making a vague reference to “this product” and showing a generic looking can of Copenhagen snuff on its marketing pieces, Altria may be trying to circumvent the MRTP review process for its other Copenhagen products by hoping that there will be a “spillover effect,” where consumers misinterpret the modified risk message to apply to all Copenhagen products.

To further our point, the coupon offer in the proposed direct mail piece is for “any style of Copenhagen.” If Altria meant for the modified risk message to switch smokers specifically to the Copenhagen Snuff Fine Cut product that is the subject of this application, then the coupon – a financial incentive to drive purchases – should be provided only for this specific product. Otherwise, Altria should have submitted applications for all of its Copenhagen brand products.

Similarly, Altria’s plan to place a sign with the modified risk message in retail stores “behind the checkout counter and within 48” of where ST products are sold<sup>104</sup> and not placed specifically where Copenhagen snuff Fine Cut is displayed also leaves open the possibility that viewers will mistakenly believe that “this product” referenced in the proposed point-of-sale

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<sup>102</sup> “Over the time period of the epidemiology studies, the candidate product occupied a sizeable market share among MST products. For this reason, and the reasons presented above, we conclude that the health risks of the candidate product can be sufficiently assessed using existing epidemiology data for U.S. smokeless tobacco products.” Altria Briefing Document, at 18-20.

<sup>103</sup> FDA Briefing Document, at 13.

<sup>104</sup> Altria, 4.1: Labels, Labeling, and Advertising, at 6.

sign<sup>105</sup> refers to the Copenhagen brand family, not to the specific style that is the subject of this application. In a worst-case scenario, if the sign is far enough away from where shoppers can adequately see the image of the product and placed with other brands of moist snuff, then consumers could mistakenly believe that the sign refers to any moist snuff product being displayed.

The lack of specificity about what product the proposed modified risk message applies to also has implications for youth smokeless tobacco users, for which Copenhagen has been a top smokeless tobacco brand.<sup>106</sup> FDA found that “the applicant’s analysis of PATH Wave 1 Study data found that only 1.5% of 12-17-year-old past 30-day non-light smokeless tobacco users (those who reported using smokeless tobacco more than ten times in their lifetime and last used smokeless tobacco within the past 30 days) used a “Copenhagen Snuff” product as the type of Copenhagen brand usually or most recently used. When expanding the analysis to any Copenhagen product, FDA found that 40.8% (CI: 32.8%-49.3%) of 12-17-year-old past 30-day non-light users reported Copenhagen as their usual or most recent brand used.”<sup>107</sup> Ambiguity about the style of Copenhagen product to which the modified risk claim applies may increase youth interest in using this brand overall.

Because the application is for one specific style of Copenhagen, and the proposed marketing materials are not specific about the modified risk message applying exclusively to Copenhagen Snuff Fine Cut, if FDA grants the application, it will be important for the post-market surveillance to monitor the preferences among youth of all Copenhagen brand styles, and overall, so that it can determine if youth are moving to any Copenhagen brand as a result of the modified risk messaging and marketing, or if youth are moving to Copenhagen Snuff Fine Cut specifically. Since the National Survey on Drug Use and Health has stopped asking youth participants who use smokeless tobacco about their preferred brands,<sup>108</sup> it will be important for another survey to capture youth preference for brands.

Respectfully submitted,

American Academy of Pediatrics  
American Cancer Society Cancer Action Network  
American Heart Association  
American Lung Association  
Campaign for Tobacco-Free Kids  
Truth Initiative

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<sup>105</sup> Altria, 4.1: Labels, Labeling, and Advertising, at Appendix 4.1-9.

<sup>106</sup> Analysis of data from the National Household Survey on Drug Abuse and National Survey on Drug Use and Health, SAMHSA, HHS, Center for Behavioral Health Statistics and Quality.

<sup>107</sup> FDA Briefing Document, at 31.

<sup>108</sup> Substance Abuse and Mental Health Administration, National Survey on Drug Use and Health: 2014 and 2015 Redesign Changes, August 2015, <https://www.samhsa.gov/data/sites/default/files/NSDUH-RedesignChanges-2015.pdf>, at 21.